

### **REMARKS**

Applicants respectfully traverse the rejections in the outstanding Office Action, and request that they be withdrawn in view of the following Remarks. Applicant has amended claims 1 and 12 to make it clear that the cuvette is cleansed by different cleaning operations depending upon what assay is scheduled to be next performed therein

#### ***Claim Rejections – 35 USC §102***

Claims 1 and 12 are rejected under 35 USC 102(b) as being anticipated by a new reference, Bell (US 5,679,309). The Examiner cites Bell as disclosing “cleaning the used cassette before a first group and a second group of assays have been scheduled to be next performed in the cuvette, and cleaning the (used) cassette when a first group and second group of assays have been previously performed in the cuvette.” As best understood, the Examiner appears to be saying that Bell cleans a used cassette before and after a first group and a second group of assays are performed in the cuvette.

This is not what is claimed in claims 1 and 12. Claim 1 considers the assay scheduled to be next performed in a cuvette after it is cleaned and then uses different cleansing operations depending on whether the assay is in a first or second group. For example, on page 15, about 5 lines down in paragraph [0045], the wash station cleans a cuvette with four cleansing operations (if the next assay to be performed therein is in a first group) but, for purposes of efficiency, cleans the cuvette with only three operations if the next assay to be performed therein is in a second group.

In contrast, Bell has a single wash station and (apparently) uses the same cleaning operation on all used cassettes (because there is no mention or hint or varying operation of the wash station). That is, Bell never “looks ahead” to see what assay will be next performed in a used cassette and adjusts the cleaning operation accordingly, as claimed in claims 1 and 12. In Fig. 5 and Col. 3, lines 31-57, Bell discloses washing a first used cassette (when a target cuvette is at a first reagent addition station) or washing a second

used cassette (when a target cuvette is at a second reagent addition station). Bell's objective to maximize "opportunistic washing" (Col. 2, lines 62-65) without adding an additional wash station (Col. 2, lines 56-59). To the end, Bell adds an additional reagent add station (Col. 3, lines 32-33), so that the frequency at which a target cuvette (a cuvette to be loaded with reagent and sample for analysis) is at either the first or second reagent add station is increased. This, in turn, increases the frequency for "opportunistic washing" while adding reagent (Col. 3, lines 63-67). Since Bell does not disclose identifying the assay scheduled to be next performed in a (used) cuvette before cleaning it and then using different cleansing operations depending on whether the assay is in a first or second group, Bell cannot be said to anticipate claims 1 and 12. Accordingly, the rejection of claims 1 and 12 under 35 USC 102(b) as being anticipated by Bell is unfounded and Applicant respectively requests it be withdrawn.

Claims 1 and 12 are rejected under 35 USC 102(b) as being anticipated by a new reference, Devlin (US 2004/0115095 A1). The Examiner cites Devlin for teaching a method for cleaning a used reaction cuvette. Devlin, however is addressing a problem that occurs when washing a cuvette is not sufficient to eliminate all residues and residues in a washed used cuvette can adversely affect the results of certain sensitive assays and does not vary the cleaning condition of a cuvette depending upon what assay is scheduled to be next performed therein. From paragraph 26:

However, washing techniques that are feasible for installation on automated analyzers 10 cannot ensure that all vestiges of liquid contamination possibly remaining in a washed cleaned cuvette 24 are totally removed, thereby making it possible for extremely small residues of reagents or other possible contaminants to be present in a cleaned used cuvette 24. Unfortunately, certain highly sensitive assays may have inaccurate results if conducted in a reused cuvette 24 having any amount of contaminants from a preceding assay are present in a cleaned used cuvette.

To solve this problem, Devlin defined "illegal-pairs" of assays such if the residue of a previous A assay reagent (in a now cleaned cuvette) adversely affects the results of a B assay schedule to be carried out in that particular cleaned used cuvette 24, then the cleaned cuvette is rejected and a new cuvette is used instead. Again from paragraph 26:

For reasons of analytical accuracy, in accordance with a key feature of the present invention, in the event an illegal A-B pair is formed, it is not permissible to conduct a B assay in a cuvette 24 that has just previously been used to conduct an A assay even if cuvette 24 has been cleaned.

In operation, as described in paragraph 23 all of Devlin's used cuvettes enter the same cuvette wash station, are washed (presumably in the same manner because there is no mention or hint of varying operation of the wash station) and dried, and inventoried within a cleaned used cuvette store. That is, Devlin simply washes all cuvettes and then rejects some because a highly sensitive assay would otherwise be performed therein. Since, Devlin never "looks ahead" to see what assay will be next performed in a used cassette and adjusts the cleaning operation accordingly, as claimed in claims 1 and 12. Devlin cannot be said to anticipate claims 1 and 12. Accordingly, the rejection of claims 1 and 12 under 35 USC 102(e) as being anticipated by Devlin is unfounded and Applicant respectfully requests it be withdrawn.

### ***Claim Rejections – 35 USC §103***

Claims 2-5, 13 and 14 are rejected under 35 USC 103(a) as being unpatentable over Bell or Devlin et al in combination with Sakagami (US Patent 4,785,407) and Jordan (US Patent 4,325,910).

The Examiner turns to Sakagami for teaching detecting the dirtiness level of a cuvette and rewashing a cuvette having dirtiness above a threshold level (Col. 5, lines 14-32). The Examiner also cites Jordan for teaching washing and drying a cuvette and discharging wash liquid (Col. 12, lines 45-48; Col. 13, lines 12-17) and concludes that it would have been obvious for one skilled in the art to use the wash-dry-discharge steps taught by Jordan in the dirtiness detecting scheme taught by Sakagami in Bell or Devlin et al's, cleaning process to "improve the cleaning process."

While that may be true, neither Bell nor Devlin et al, as discussed supra, "look ahead" to see what assay will be next performed in a used cassette that is to be cleaned and adjust the cleaning operation accordingly, as claimed in claims 1 and 12. In addition, both Bell and Devlin et al. have a single wash station and there is never a mention of changing washing operations. Consequently, the proposed modification of Bell or Devlin et al. using the Sakagami and Jordan references fail to teach Applicant's used cuvette washing scheme in which different washing conditions are employed depending upon the identity of the assay scheduled to be next performed therein.

The significance of the Examiner's statement that "The assays as claimed are inherent in Bell and Devlin et al. system." is not fully understood. Certainly Bell and Devlin et al.'s analyzers can perform assays. However, as explained above, the identity of the particular assay to be next performed in a cuvette to be cleaned is a key element of the present invention which varies the cuvette cleaning conditions depending upon the assay to be next performed therein. Accordingly, the rejection of claims 2-5, 13 and 14 under 35 USC 103(a) as being unpatentable over Bell or Devlin et al in combination with Sakagami and Jordan is unfounded and Applicant respectfully requests it be withdrawn.

As explained in depth herein, Applicant respectfully submits that the combination of Bell, Devlin et al, Sakagami and Jordan do not anticipate nor render claims 1 and 12 obvious because no combination of the references teach Applicant's method for cleansing a used reaction cuvette with either a first or a second different series of cleansing operations depending upon what assay is scheduled to be next performed in the to-be-cleaned, used cuvette. Furthermore, the difference or differences in the claim over the applied references, and the proposed modification of the applied reference cannot replicate Applicant's cleaning method. Accordingly, Applicant respectfully submits that the claims are allowable over the prior art, and requests removal of this rejection.

**Conclusion**

Applicants believe that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicant's representative at the number provided below.

Respectfully submitted,



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